Replication Medical Vessel Guard
510(k) Summary
K082782

APR - 2 2009

Device Manufacturer: Replication Medical, Inc.
7 Clarke Drive
Cranbury, NJ 08512

Submission Date: September 11, 2008

Contact Person: Ann Prewett
Tel: 609-860-0330 Fax: 609-860-0343

Proprietary Name: Replication Medical Vessel Guard

Common Name: Vessel Guard

Device Class: Class III

Product Codes: MFX

Device Description and Intended Use:

The Replication Medical Vessel Guard is indicated as a cover for vessels following anterior vertebral surgery. The Vessel Guard is available in several sizes and is manufactured from biocompatible materials.

Technological Characteristics

The Replication Medical Vessel Guard is similar to legally marketed devices as listed below in that they share similar indications for use and incorporate similar technological characteristics. Biocompatibility testing was conducted and the testing indicated that the material is suitable for long term implantation. Suture pullout testing was also performed and the testing confirmed that the Vessel Guard is equivalent to predicate devices.

Substantial Equivalence Information:

The Replication Medical Vessel Guard is similar to the devices listed in the table below.

Trade/Proprietary Name	Manufacturer	510(K) #	Clearance Date
PRECLUDE Vessel Guard	W.L. Gore & Associates, Inc	K061727	8/7/2006
PRECLUDE IMA Sleeve	W.L. Gore & Associates, Inc	K960532	5/23/1996

The safety and effectiveness of Vessel Guard is based upon the determination of the substantial equivalence as well as the safety and effectiveness of its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 2 2009

Replication Medical Inc.
c/o M Squared Associates, Inc.
901 King Street
Suite 200
Alexandria, VA 22314
Attn: Mr. Marcos Velez-Duran

Re: K082782
Trade Name: EnGuard™ Vessel Guard
Regulation Number: 870.3470
Regulation Name: Intracardiac patch or pledget
Regulatory Class: II
Product Code: OMR
Dated: February 24, 2009
Received: February 25, 2009

Dear Mr. Velez-Duran:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling and any promotional materials:

The safety and effectiveness of this device for reducing the incidence, severity, and extent of post-operative adhesion formation have not been established.

Furthermore, the indication for use as a cover for vessels following anterior vertebral surgery must be prominently displayed in all labeling, including pouch box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your

responsibilities under the Act from the Division of Small Manufacturers, International, and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Christy Foreman for

Donna-Bea Tillman, Ph.D., M.P.A.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082782

Device Name: EnGuard™ Vessel Guard

Indications For Use: The EnGuard™ Vessel Guard is indicated as a cover for vessels following anterior vertebral surgery.

Prescription Use ✓ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Mahnen

(Division Sign-Off)
Division of Cardiovascular Devices

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